

The reinforcing mesh is made by a conventional braiding process. In such a process, the braid members are interwoven, under tension, around the inner wall. The outer wall is then applied by dipping, spraying, extrusion or any other suitable process.

Webster, Jr., at column 3, lines 7-11. Webster, Jr. shows in Figure 2 that a number of axial members 28 are braided into a braid including helical members 26. The interweaving of the axial and helical members together causes the axial members 28 to sometimes be entirely on the outside of the braid, where the axial members are directly pressed against the outer polymer layer of the catheter, and at other locations, the axial members are entirely on the inside of the braid, so the axial members are directly pressed against the inner polymer layer. Applicants have attached to this amendment a highlighted photocopy of Figure 2 of Webster, Jr., highlighting locations where this occurs. At these locations, the axial members will be subject to adhesion with either the inner or outer layer along a relatively long axial distance. Therefore, at these locations, an axial member is likely to become strongly adhered to the outer or inner polymer layer, depending on whether the axial member is forced to the outside or the inside.

Applicants recite in claim 1 a device including an axial member disposed between the helical members. This structural limitation interrupts the relatively long axial distances along which the axial member is in contact with one or the other of the inner or outer polymer layers. The functional language recited in claim 1, specifically stating that the axial member limits elongation of the catheter under tension but does not substantially reduce catheter flexibility, is a mere reflection of the characteristics of the catheter caused at least in part by this structural limitation. Because Webster, Jr. suggests braiding the axial members into the overall braid, this recited structure is missing from the reference. By braiding the axial and helical members in a conventional braid, Webster, Jr., constructs a catheter having less flexibility as noted, for example, in column 3, lines 1-6.

Applicants have already described how the additional structural limitation requires changes in the fabrication process of prior catheters:

As mentioned above, the helical members 32 are braided over a carrier with the axial member 34 therebetween. Although braiding helical members is well known in the art, positioning an axial member between the helical members requires some modification to conventional braiding machines. For example, a conventional Steeger braiding machine may be modified to incorporate an individual bobbin carrier that delivers the axial member 34 through a horn gear

shaft. The axial member 34 carrier is retrofitted onto the horn gear. With this arrangement, one of the helical member 32A carriers is allowed to pass under and the other helical member 32B carrier is allowed to pass over the axial member 34. The net result is a braid reinforcement structure 50 comprising two or more interwoven helical members 32, with an axial member 34 disposed therebetween.

Specification at page 14, lines 7-17. The illustrative fabrication technique highlights the novelty of the devices as claimed, though it is not necessary to limit the present invention to this one fabrication technique.

Because Webster, Jr., fails to disclose a reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member and an axial member disposed between the first helical member and the second helical member, instead weaving the axial member into the braid, Applicants believe that claim 1 is clearly patentable over Webster, Jr.

In light of the above remarks and because the claims include further recitation of distinct elements, Applicants believe dependent claims 2-4, 6 and 11, which depend from claim 1, are patentable over Webster, Jr.

Independent claim 13 likewise recites a catheter including a reinforcement layer having characteristics similar to those noted above with respect to claim 1. Therefore, for like reasons, Applicants believe that independent claim 13, and dependent claims 14, 15 and 17, are also clearly patentable over Webster, Jr.

In paragraph 2 of the Office Action, the Examiner rejected claims 5, 7-8, 16 and 18 under 35 U.S.C. §103(a) as being anticipated by Webster, Jr., in view of Stinson, U.S. Patent No. 5,891,191. After careful review of the cited references, Applicants respectfully disagree.

Webster, Jr., has been discussed above. Applicants note that each claim rejected under the combination of Webster, Jr., in view of Stinson, incorporates the recitations of either claim 1 or 13, each of which is believed patentable over Webster, Jr., at least because Webster, Jr., fails to disclose a reinforcement layer including an axial member disposed between the helical coils of the braided layer. The Examiner appears to have cited Stinson to suggest the use of monofilaments. While Applicants do not believe that one would find it obvious to use materials used in a stent to construct a reinforcement layer for a catheter, as the devices have distinct purposes and must overcome different difficulties, Applicants also note that Stinson does not

appear to suggest, and the Examiner has not stated that Stinson does suggest, axial members as recited in either of claims 1 or 13. Therefore, both claims 1 and 13 are believed patentable over Webster, Jr., in view of Stinson.

Because the independent claims (1 or 13) from which claims 5, 7-8, 16 and 18 each depend are believed patentable over the cited combination, claims 5, 7-8, 16 and 18 are all believed clearly patentable over Webster, Jr., in view of Stinson.

In paragraph 3 of the Office Action, the Examiner rejected claim 12 under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. in view of Ken et al., U.S. Patent No. 5,749,891. On close review of the cited references, Applicants respectfully disagree.

Webster, Jr., is discussed above particularly noting that claim 1 is patentable over Webster, Jr. Applicants again do not believe that one of skill in the art would find it obvious to rely on materials used in a vaso-occlusive coil to construct a catheter reinforcement layer, the devices having distinct purposes and encountering very different difficulties. Applicants also note that Ken et al. do not appear to include suggestions for axial members placed between the helical members of the vaso-occlusive coils.

In light of the above, Applicants believe that independent claim 1 would be patentable over Webster, Jr. in view of Ken et al. Therefore, Applicants also believe that dependent claim 12 is clearly patentable over Webster, Jr., in view of Ken et al.

In paragraph 4 of the Office Action, the Examiner rejected claims 9-10, 19-21 and 23-28 under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr., in view of Martin et al., U.S. Patent No. 6,361,637. After careful review of the cited references, Applicants respectfully disagree.

Webster, Jr., is discussed above particularly noting that Webster, Jr., does not suggest or disclose a reinforcement member including braided helical members having an axial member disposed between the helical members in the braid. Martin et al. appear to suggest a kink-resistant stent-graft. Applicants again question whether anyone of skill in the art would look to a stent-graft device to find materials or constructions for use in making a reinforcing layer for a catheter shaft, the devices having distinct purposes and encountering distinct difficulties. However, Applicants note that the Examiner has only cited Martin et al. for the purpose of illustrating the provision of a liquid crystal polymer monofilament in a flat ribbon. Applicants

also note that Martin et al. do not appear to suggest the provision of any axial members in their stent, instead using radially disposed ribbons that are axially spaced from one another, for example, in Figure 1B, which shows ribbons 23 radially disposed with an axial spacing 24 therebetween.

In light of the above, Applicants believe that independent claims 1 and 13 would be clearly patentable over the cited combination. Therefore, Applicants likewise believe that dependent claims 9-10 and 19-21 are clearly patentable over Webster, Jr., in view of Martin et al.

With respect to claims 23-28, each of the independent claims 23, 25 and 28 recites a braid including first and second helical members with an axial member disposed between the first and second helical members. It has been noted above that Webster, Jr., does not provide a suggestion for such a braid, and Martin et al. do not appear to suggest the provision of any axial members as recited in a braided catheter reinforcement layer. Therefore, for reasons similar to those stated above with respect to claims 1 and 13, and other reasons, each of claims 23-28 is believed patentable over Webster, Jr. in view of Martin et al.

Reconsideration, reexamination, and allowance of all pending claims 1-21 and 23-28 are respectfully requested. Issuance of a notice of allowance in due course is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

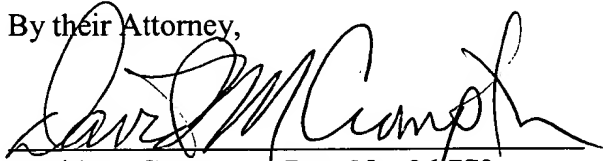
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Respectfully submitted,

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